UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA
Civil No. 15 - 2168

UNITED STATES OF AMERICA, Plaintiff v. MEDTRONIC INC., a corporation, and S. OMAR ISHRAK and THOMAS M. TEFFT, individuals, Defendants.	COMPLAINT FOR PERMANENT INJUNCTION

INTRODUCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin Medtronic Inc. (“Medtronic”), a corporation, and S. Omar Ishrak, and Thomas M. Tefft, individuals (hereinafter, collectively, “Defendants”) from violating:

A. 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of devices, as defined by 21 U.S.C. § 321(h), that are adulterated within the meaning of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, and

installation are not in conformity with current good manufacturing practice requirements prescribed at 21 C.F.R. Part 820;

B. 21 U.S.C. § 331(k), by causing devices to become adulterated within the meaning of 21 U.S.C. § 351(h), as described in paragraph A above, while such devices are held for sale after shipment in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Medtronic is incorporated under the laws of Minnesota. Medtronic Neuromodulation ("Medtronic Neuro"), a business unit of Medtronic, manufactures medical devices, including but not limited to, SynchroMed II implantable infusion pumps. The headquarters of Medtronic Neuro is located at 7000 Central Ave. NE, Minneapolis, MN 55432, and its manufacturing facility is located at 53rd Avenue, NE, Columbia Heights, MN 55421.

5. S. Omar Ishrak is Medtronic's Chairman and CEO. He is the most responsible person at the firm, and oversees the firm's product development, product management, and international relations and sales. He performs his duties at 710 Medtronic Parkway, Minneapolis, MN 55432.

6. Thomas M. Tefft is the Senior Vice President of Medtronic, and the President of Medtronic Neuro. He is the most responsible person at Medtronic Neuro,

and oversees the business unit's product development, research, regulatory compliance and marketing. He performs his duties at 7000 Central Ave. NE, Minneapolis, MN 55432.

7. Defendants have been, and are now, manufacturing and distributing in interstate commerce various articles of devices, as defined by 21 U.S.C. § 321(h), including, but not limited to, SynchroMed II implantable infusion pumps, the subject of this injunction.

8. Defendants' products are devices, within the meaning of 21 U.S.C. § 321(h), in that they are intended to affect the structure or any function of the body of man.

LEGAL STANDARDS

9. A device must be manufactured, packed, stored, and installed in conformity with good manufacturing practice to ensure its safety and effectiveness. 21 U.S.C. § 360j(f). The statutory good manufacturing practice requirement is set out in the quality system ("QS") regulation for devices, 21 C.F.R. Part 820. A device that has been manufactured, packed, stored, or installed in violation of this requirement is deemed to be adulterated. 21 U.S.C. § 351(h).

10. The introduction or delivery for introduction into interstate commerce of an adulterated article of device is a violation of the Act, 21 U.S.C. § 331(a).

11. The adulteration of a device while it is held for sale after shipment in interstate commerce constitutes a violation of the Act, 21 U.S.C. § 331(k).

APRIL 2013 INSPECTION

12. FDA inspected Medtronic Neuro's manufacturing facility on February 14 – April 3, 2013 ("April 2013 inspection"). During the April 2013 inspection, the FDA investigators documented numerous violations of the QS regulation at Medtronic Neuro. Many of these violations related directly to the manufacture of the SynchroMed II implantable infusion pump. FDA investigators observed the following violations of the QS regulation set forth in 21 C.F.R. Part 820:

A. Defendants fail to establish and maintain adequate design validation procedures to ensure that devices conform to defined user needs and intended uses, to complete proper risk analysis, and to document the results of the validation, in violation of 21 C.F.R. § 820.30(g);

B. Defendants fail to establish and maintain adequate procedures to include requirements for identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems, in violation of 21 C.F.R. § 820.100(a)(3);

C. Defendants fail to establish and maintain adequate procedures to include requirements for verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device, in violation of 21 C.F.R. § 820.100(a)(4);

D. Defendants fail to establish and maintain procedures for implementing corrective and preventive action, in violation of 21 C.F.R. § 820.100(a);

E. Defendants fail to establish and maintain procedures for verifying the device design, in violation of 21 C.F.R. § 820.30(f);

F. Defendants fail to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, in violation of 21 C.F.R. § 820.30(i); and

G. Defendants fail to establish and maintain procedures to control product that does not conform to specified requirements, in violation of 21 C.F.R. § 820.90(a).

PRIOR INSPECTIONS

13. FDA inspected Medtronic Neuro's facilities previously in May 2012, January 2011, January 2007, and June 2006. At these inspections, FDA repeatedly observed and documented violations of the QS regulations similar to those cited above during the April 2013 inspection, including, but not limited to, violations involving: design controls (21 C.F.R. § 820.30) and corrective and preventive action (21 C.F.R. § 820.100).

14. At the conclusion of each of the prior inspections, the FDA investigators issued a Form FDA 483 detailing Defendants' numerous violations of the Act to Defendants, and discussed the documented observations with them. Defendants promised corrections at the conclusion of each inspection.

PRIOR NOTICE OF VIOLATIONS

15. Defendants are well aware that their practices violate the Act. FDA has repeatedly warned Defendants, both orally and in writing, about their violative conduct, and has emphasized the importance of Defendants' compliance with the Act.

16. FDA issued a Warning Letter dated July 17, 2012 to Defendants, following the May 2012 inspection of the Medtronic Neuro facility. The letter discussed the QS violations involving corrective and preventive actions and complaint handling (21 C.F.R. § 820.198) observed at the inspection. The letter also warned Defendants that further enforcement actions, including injunction, could occur if they did not correct the violations.

17. Defendants also received Warning Letters, dated July 3, 2007 and August 29, 2006, following the January 2007 and June 2006 inspections. These letters also addressed the numerous QS violations, including but not limited to design controls and corrective and preventive action, observed during the inspections and warned of further enforcement actions if corrections were not made.

18. Representatives of Medtronic also attended a meeting with FDA’s Center for Devices and Radiological Health and Minneapolis District Office on January 31, 2013. At this meeting, Defendants stated that they were aware of the violations at their facilities and were taking steps to correct them.

19. At the conclusion of each of FDA's inspections of the firm, the FDA investigators issued a Form FDA 483 detailing Defendants' various violations of the Act

to a responsible individual at the firm and discussed the documented observations with the recipient.

20. Defendants made promises to correct their violations in written responses to the April 2013 inspection, dated April 24, and several follow-up responses, detailing how and when the corrections promised in the April 24 letter had been made. None of these responses contained adequate evidence that Defendants have corrected their deviations.

21. Based on Defendants' conduct, Plaintiff believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a) and (k).

WHEREFORE, Plaintiff prays:

I. That Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be permanently restrained and enjoined pursuant to 21 U.S.C. § 332(a) from directly or indirectly:

A. violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, any article of device that is adulterated within the meaning of 21 U.S.C. § 351(h); or

B. violating 21 U.S.C. § 331(k), by causing any article of device to become adulterated within the meaning of 21 U.S.C. § 351(h) while such devices are held for sale after shipment in interstate commerce.

II. That the Court order Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, to cease directly and indirectly manufacturing, packing, labeling, and distributing (domestically and internationally) SynchroMed II implantable infusion pumps at or from its Medtronic Neuro facilities, unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute the SynchroMed II implantable infusion pumps are established, operated, and administered in compliance with 21 U.S.C. § 360j(f)(1) and the Quality System regulation prescribed in 21 C.F.R. Part 820, and in a manner that has been found acceptable to FDA; and

III. That the Court authorize FDA, pursuant to this injunction, to inspect Defendants' Medtronic Neuro facility to ensure continuing compliance with the terms of this injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are performed.

IV. That Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

ANDREW M. LUGER
United States Attorney

s/ Chad A. Blumenfield
CHAD BLUMENFIELD
Assistant U.S. Attorney
Attorney ID 387296
600 Courthouse
300 South Fourth St.
Minneapolis, MN 55415

Ross S. Goldstein
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
Civil Division
P.O. Box 386
Washington, DC 20044

OF COUNSEL:

WILLIAM B. SCHULTZ
Acting General Counsel

ELIZABETH DICKINSON
Associate General
Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel,
Litigation

TARA BOLAND
Associate Chief Counsel
United States Department of
Health and Human Services
Office of the General Counsel
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
(301) 796-8549